K050727
Page 1 of 2

JUN 13 2005

SECTION 7
510(K) SUMMARY OF SAFETY EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The contents of this 510(k) summary have been provided in conformance with 21 CFR §807.92.

Date:	March 18, 2005
Common/Usual Name:	Dialyzer with High Permeability Hemodialysis System
Trade/Proprietary Name:	NxStage Cartridge Express
Classification Name:	High Permeability Hemodialysis System (21 CFR 876.5860)
Device Classification:	Class II
Product Code:	78 KD I – Dialyzer, High Permeability with or without Sealed Dialysate System
Device Panel:	Gastroenterology-Urology (GU)/Gastro-Renal (GRDB)
510(k) Sponsor & Owner/Operator:	NxStage Medical, Inc 439 South Union St, Suite 501 Lawrence, MA 01843 **Owner/Operator No. 9045797** **Establishment Registration #3003464075**
Contact Person:	Norma LeMay Manager, Regulatory Affairs

Device Description:
The NxStage System One consists of the NxStage Cycler and the NxStage Cartridge Extracorporeal Blood and Fluid Circuit.

The NxStage Cycler is an electro-mechanical device that interfaces with the NxStage Cartridge. The NxStage Cartridge is a single-use extracorporeal blood circuit and fluid management device that mounts integrally within the NxStage Cycler. The NxStage

Cartridge Express is a single-use extracorporeal blood circuit and fluid management device with a pre-attached high flux (permeability) hollow-fiber filter.

The System (and all components) is intended for treatment of renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration in both acute and chronic environments, as prescribed by the treating physician.

Substantial Equivalence:
This submission is a Special 510(k) Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), NxStage has provided certification of compliance to 21 CFR 820.30 Design Control requirements. Design validation testing has been performed to ensure that the modified device meets design specifications. The modified NxStage Cartridge Express has been compared to the baseline as cleared in K032356 and found to be substantially equivalent.

Conclusion:
Based on the device indications for use, comparison of descriptive and technological characteristics, and design control certification, the modified NxStage Cartridge Express has been shown to meet the minimum requirements that are considered acceptable for its intended use and is substantially equivalent to the baseline device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2005

Ms. Norma LeMay
Manager, Regulatory Affairs
NxStage Medical, Inc.
439 South Union Street, Suite 501
LAWRENCE MA 01843

Re: K050727
Trade/Device Name: NxStage Cartridge Express
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: May 12, 2005
Received: May 13, 2005

Dear Ms. LeMay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K050727

Device Name: NxStage System One with Cartridge Express

Indications for Use: *The NxStage System One is indicated for treatment of renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration. All treatments must be administered by a health care provider, under physician's prescription.*

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lipman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050727